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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/652,001	08/31/2000	Alan Krasberg	P56156	2933

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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 04/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/652,001

Applicant(s)
Krasberg

Examiner
Joseph Weiss

Art Unit
3761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 20, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above, claim(s) 33-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 20) ☐ Other:

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DETAILED ACTION

1. Applicant's election with traverse of claims 1-32 & 61 in Paper No. 5 is acknowledged.
2. This application contains claims 33-60 drawn to an invention non-elected with traverse in Paper No. 4. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1-32 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and intended results language. The steps which go to make up the invention must be clearly and positively specified. The steps must be organized and correlated in such a manner as to present a completely operative process.

6. Claim 1 recites the limitation "the concentration" in line 2. There is insufficient antecedent basis for this limitation in the claim.

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7. Claim 1 recites the limitation "the tissue" in line 2. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 1 recites the limitation "the background" in line 3. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 24 recites the limitation "the air" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Furthermore, air is not present in the atmosphere of the chamber, but instead a special gas composition of only oxygen & fuel gas is present, thus referring to this gas composition as "air" is incorrect, hence indefinite.

10. Claim 28 recites the limitation "the ventilation system" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Furthermore, in regards to claim 28, applicant sets forth supplying said first fuel gas into the ventilation system of a building to provide the breathable composition inside the building. In light of the prior claim limitations this limitation is indefinite. The first fuel gas is blended with oxygen to create a "breathable composition" therefore applicant needs to set forth the provision of the composition and not the fuel gas in order to properly further define the invention or set forth the prior step as being optional or an intervening step of fuel gas & oxygen separation. See claim 31 for the correct manner to set forth what appears to be applicant's invention.

11. Claim 29 recites the limitation "the respiratory system" in line 2. There is insufficient antecedent basis for this limitation in the claim.

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Furthermore, in regards to claim 29, applicant sets forth supplying said first fuel gas to the respiratory tract of the animal to provide the breathable composition upon inhalation of the fuel gas and ambient air. In light of the prior claim limitations this limitation is indefinite. The first fuel gas is blended with oxygen to create a "breathable composition" therefore applicant needs to set forth the provision of the composition and not the fuel gas in order to properly further define the invention or set forth the prior step as being optional or an intervening step of fuel gas & oxygen separation. See claim 31 for the correct manner to set forth what appears to be applicant's invention.

12. Claim 32 recites the limitation "the rate" in line 2. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 32 recites the limitation "the inhaled breathable composition" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Does applicant mean "inhaleable," usage of inhaled connotes that the gas must first be inhaled by the user.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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15. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Stamler et al (US 6314956).

In regards to claim 1, Stamler discloses the intentional “artificial” increase of a concentration of a first fuel gas compound in animal tissue above “background” (i.e. normal levels from std atmospheric air composition) in tissue. (Note administration of ethyl nitrite which has several different secondary metabolites which are/can be considered “fuel gases” as set forth by applicant) and therefore inherently reduces Reactive Oxygen Species (ROS) in the tissue.

In regards to claim 2, Stamler discloses human use of the device/method disclosed.

In regards to claims 3-5, Stamler discloses delivery of the medicament that causes this change in tissue concentration of the fuel gasses to a user in excess of time period of an hour, a day or a month. (Col. 4 lines 34-36 range is from 1 min to two **or more days**, e.g. 28 more days, thus a month).

In regards to claim 6, Stamler discloses such (again not that administration of ethyl nitrite creates several different secondary metabolites which are/can be considered “fuel gases” as set forth by applicant which will diffuse into the tissues). Furthermore, Stamler discloses the co-commitment delivery of oxygen, a commonly known fuel gas, which would also result in raising oxygen levels in tissue above “background.”

In regards to claim 7, Stamler’s medicament will break down into secondary metabolites in tissue to produce ethane.

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16. Claims 1-3, 6-10, 13, 17, 19, 21, 23-24 & 61 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Delauze et al (WO96/06771) . See English language = US 6138670

In regards to claims 1, 6 & 8, Delauze discloses a first fuel gas (hydrogen) that will result in an increase of such gas in a user's tissue providing oxygen supplemented with a first fuel gas. (See abstract), and this co-commitment delivery of oxygen, a commonly known fuel gas, which would also result in raising oxygen levels in tissue above "background" thus meeting the limitations of claim 6 and therefore inherently reduces the ROS in the tissue.

In regards to claims 2 & 9, the animal is human (diver).

In regards to claims 3 & 10, exposure discloses as greater than an hour (page 6 lines 3-10).

In regards to claim 7 & 13, the first fuel gas is hydrogen (see abstract).

In regards to claim 17, the pressure of the gas is provided at or "near" atmospheric pressure.

In regards to claim 19, the circuit is "closed." (page 4 lines 35-36)

In regards to claim 21, the chamber has an open bottom (page 9, lines 3-5) & a gas enhanced with hydrogen would be "lighter than air" and the animal is exposed to the gas in the chamber.

In regards to claim 23, the animal is a person who may enter the chamber from the bottom opening. (Page 9 lines 3-5)

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In regards to claim 24, Delauze discloses the use of carbon dioxide scrubbing. (Page 12 line 10)

In regards to claim 61, the exposure is under hyperbaric conditions. (Page 7 lines 15-20)

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 18, 20, 25, 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delauze.

In regards to claims 18 & 20, Delauze substantially discloses the instant application's claimed invention, but does not explicitly disclose use of open or semi-closed loop/circuit systems, albeit the use of "closed loop" is qualified as only being the preferred mode, thus by implication the disclosed invent may also utilize other old, well known and common loop systems, e.g. open & semi-closed. Use of semi-closed and open loop/circuits is old and well known in the art and are considered in the art to be interchangeable equivalents, therefore one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

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In regards to claim 25, the reference noted above substantially disclose the claimed invention except for the breathable composition comprising 66% hydrogen by volume.

It is noted that applicant's specification does not set forth such, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 27, the reference noted above substantially disclose the claimed invention except for the breathable composition having a density of about 75% of that of ambient air.

It is noted that applicant's specification does not set forth such, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

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Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 28, the supplementation of building/structure ventilation systems with supplemental gasses is old & well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

(E.g. airplanes & Hospitals)

In regards to claim 29, the gas of Delauze is breathable, deliverable with ambient air.

In regards to claim 30, the use of nasal cannula as a user interface is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 31, the use of an oro-nasal mask or helmet as a user interface is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 32, the delivery of gas as a rate to insure the gas is delivered at a rate that will insure a desired concentration, e.g. therapeutic, is old and well known in the art, and one

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of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

19. Claims 4-5 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delauze as applied to claim 3 & 10 above, and further in view of Gardner et al (Spacecraft Maximum Allowable Concentrations for Selected Airborne Contaminants, Vol. 1, 1994).

In regards to claims 4-5 & 11-12, Delauze substantially discloses the instant application's claimed invention, but does not explicitly disclose exposure for greater than a day or greater than a month. However, Gardner discloses such (see exposure charts for hydrogen & methane on pages 140 & 145 respectively). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Gardner and used them with the invention of Delauze. The suggestion/motivation for doing so would have been to expose the user to the gas over a given & proscribed time period for study, analysis and evaluation. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

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20. Claims 14-15 & 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delauze as applied to claim 8 above, and further in view of Scherer et al. (US 5971934).

In regards to claims 14-15 & 26 substantially discloses the instant application's claimed invention, but does not explicitly disclose use of a second fuel gas compound, the use of acetylene or the use of an explosive composition. However, Scherer disclose such (acetylene is a fuel gas and its commonly known to be explosive)(col. 2 lines 29-42). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Scherer and used them with the invention of Delauze. The suggestion/motivation for doing so would have been to measure the cardiac output of the users, commonly known as the "acetylene maneuver" in the respiratory arts. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

21. Claims 16 & 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delauze as applied to claims 15 & 21 above, and further in view of Fife (US 4206753).

In regards to claims 16 & 22, substantially discloses the instant application's claimed invention, but does not explicitly disclose the taking of countermeasures to prevent explosions of

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the mixture. However, Fife disclose such (See abstract & supporting text of the assertion of the abstract in the written description). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Fife and used them with the invention of Delauze. The suggestion/motivation for doing so would have been to protect the users from any possible flash flame or pressure wave resulting from an explosion of hydrogen gas. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Also the examiner takes official notice of the Hindenberg disaster where a lighter than air airship (given the model name "Graf Zeppelin") named "The Hindenberg" exploded due to the mishandling of hydrogen during the 1930s in New Jersey, replayed many times as a significant historic event and popularized in several movies, therefore common sense among one of ordinary skill in the art handling hydrogen gas would, by dint of this well known disaster, have awareness of the explosive danger and take precautions to make the device used explosion proof.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

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22. Applicant's arguments filed 20 Feb 02 have been fully considered but they are not fully persuasive.

Applicant's traversal to the species election is persuasive to the extent that it is understood that the only way with which applicant's manipulation of gas partial pressure values in tissue can be facilitated is via the respiratory system. Any other manner/method of manipulation is disclaimed as per applicant's arguments that the two species are not distinct.

Applicant's arguments that the method is a common feature to all the combinations of claims is not persuasive, because the devices applicant sets forth in the restricted article claims have recognized distinct classifications, the breadth of the method of respiratory therapy set forth by applicant is expansive beyond the various restricted article claims set forth in terms of what devices can employ such a method and because the devices applicant sets forth in the restricted article claims can be used to employ other different methods of respiratory therapy. Unless applicant limits the **base claims of the methods** to providing **specific (not generic to the point the embrace entire sub-classes of devices) devices** which are in the base claims of the **article claims** which can only be used with such a method **and** proves that no other forms of device can be used because of **some inherent and claimed structural link** requiring the devices/articles in order to perform the method of respiratory therapy discloses, the restriction is proper and final. The mere recitation of generic articles as being employed by the method do not suffice as linking claims, but instead are mere permutations of the method.

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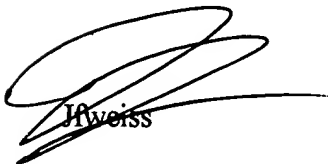
Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6283123, 6158430, 6138670, 6131571, 6123074, 5664563, 5411059
US Navy Flight Surgeon Handbook:2nd ed 1998: Toxicology
Simes et al, Elimination of Pulmonary Oxygen Toxicity, Austrailian Anaesthesia 1998
www.clean-air.org/hindenberg.htm

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

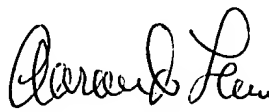
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, John G. Weiss, can be reached at telephone number (703) 308-2702. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



J. Weiss

April 12, 2002



Aaron J. Lewis
Primary Examiner